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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|----------------|----------------------|-------------------------|------------------|
| 10/798,025 | 03/11/2004 | John P. Langmore | AH-UMIC:047USDI | 6029 |
| 26271 7 | 590 08/21/2006 | | EXAMINER | |
| FULBRIGHT & JAWORSKI, LLP 1301 MCKINNEY SUITE 5100 HOUSTON, TX 77010-3095 | | | HORLICK, KENNETH R | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1637 | |
| | | | DATE MAILED: 08/21/2006 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application No. | Applicant(s) | | | |
|--|---|---|---|--|--|--|
| Office Action Summary | | 10/798,025 | LANGMORE ET AL. | | | |
| | | Examiner | Art Unit | | | |
| | | Kenneth R. Horlick | 1637 | | | |
| Period fo | The MAILING DATE of this communication apor Reply | ppears on the cover sheet with the c | orrespondence address | | | |
| WHIC - External after - If NC - Failu Any | ORTENED STATUTORY PERIOD FOR REP CHEVER IS LONGER, FROM THE MAILING It asions of time may be available under the provisions of 37 CFR 1 SIX (6) MONTHS from the mailing date of this communication. o period for reply is specified above, the maximum statutory period re to reply within the set or extended period for reply will, by statute reply received by the Office later than three months after the mailined patent term adjustment. See 37 CFR 1.704(b). | DATE OF THIS COMMUNICATION .136(a). In no event, however, may a reply be tind d will apply and will expire SIX (6) MONTHS from te, cause the application to become ABANDONE | N. nely filed the mailing date of this communication. D (35 U.S.C. § 133). | | | |
| Status | | | | | | |
| 1) | Responsive to communication(s) filed on | | | | | |
| 2a)□ | | is action is non-final. | | | | |
| 3) | ,— | | | | | |
| ,— | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | |
| Dispositi | on of Claims | | | | | |
| 4)⊠ | 4)⊠ Claim(s) <u>190-200</u> is/are pending in the application. | | | | | |
| | 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| | 6)⊠ Claim(s) <u>190-200</u> is/are rejected. | | | | | |
| | ') ☐ Claim(s) is/are objected to. | | | | | |
| 8)□ | Claim(s) are subject to restriction and/ | or election requirement. | | | | |
| Applicati | on Papers | | | | | |
| 9) 又 | The specification is objected to by the Examin | er | | | | |
| 10)⊠ The drawing(s) filed on <u>11 March 2004</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| | Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | |
| 11) | The oath or declaration is objected to by the E | | · · · · · · · · · · · · · · · · · · · | | | |
| Priority u | ınder 35 U.S.C. § 119 | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: | | | | | | |
| | 1. Certified copies of the priority documents have been received. | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| | 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | |
| | application from the International Bureau (PCT Rule 17.2(a)). | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| | | | | | | |
| Attachment | ` ' | | | | | |
| | e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) | 4) Interview Summary Paper No(s)/Mail Da | | | | |
| 3) 🛛 Infom | e of Draitsperson's Patent Drawing Review (P10-948) nation Disclosure Statement(s) (PTO-1449 or PTO/SB/08 r No(s)/Mail Date <u>6/22/04 (4 pages)</u> . | | atent Application (PTO-152) | | | |

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1. The specification is objected to because of the following informality: the continuation information must be updated to indicate issue of the parent '738 application as U.S. Patent No. 6,828,098.

- 2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.
- 3. Claim 195 is objected to because of the following informality: it lacks a period. Correction is required.
- 4. Claims 199 and 200 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

 Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 199 depends from claim 195, but the further limitation regarding a monocotyledonous plant is not further limiting. Dependency from claim 196 may be intended. Correction is required.

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5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 190-200 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are drawn to a kit comprising amplifiable DNA, wherein said DNA is defined only in how it is prepared, without any physical, chemical, or structural properties whatsoever for the DNA between the upstream and downstream adaptors. Claims of this type are referred to in Technology Center 1600 as "reach-through" claims. It is clear that applicants were not in possession of any and every possible such DNA, which might possibly be prepared at some future point using the disclosed methods, at the time of the invention; thus, these claims clearly do not satisfy the written description requirement. Such claims attempt to cover amplifiable DNA comprising every possible DNA fragment present in any possible organism; such all-encompassing sequence information is not described in the specification.

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6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 190-200 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of Walker et al. (US 5,422,252) or Rabinovitch (US 5,814,444) in view of Mullis et al. (US 4,683,195).

These claims are drawn to a kit comprising amplifiable DNA, wherein said DNA is prepared by the method specified in claim 190. This method is claimed in the patent issued from the parent '738 application. It is noted that in kit claims, which are a type of product claim, patentability is determined according to the kit component(s). A method of making or preparing a component is considered only to the extent that it materially affects the component so made or prepared. Thus, the claims read on a kit comprising amplifiable DNA, said DNA comprising fragments which have adaptor sequences at both ends. A representative embodiment of such a DNA is shown in instant Fig. 2A, structure (5).

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Walker et al. disclose a method comprising the preparation of DNA fragments which have an adaptor sequence at both ends (see entire patent, especially Fig. 1). The DNA shown at the bottom of said figure cannot be distinguished from the DNA of the claimed kit.

Rabbinovitch discloses a method comprising fragmenting DNA, ligating the fragments to adaptors, and amplifying the fragments using primers targeting the adaptor sequence (see column 3, lines 31-46). Such fragments with adaptors cannot be distinguished from the DNA of the claimed kit.

Neither of these references discloses a kit comprising the amplifiable DNA.

Mullis et al. disclose kits comprising reagents for the convenience of practicing methods requiring such reagents (see column 3, lines 34-39). At the time of the instant invention, the use of kits was clearly conventional.

One of ordinary skill in the art would have been motivated to make a kit comprising the amplifiable DNA of either of Walker et al. or Rabbinovitch because such a kit would have clearly been useful in providing for amplified DNA corresponding to said amplifiable DNA. Dependent claims 191-200 merely require that the DNA be from various known organisms, clearly not providing for any patentable consideration. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make and use the claimed kits.

7. No claims are free of the prior art.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R. Horlick whose telephone number is 571-272-0784. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kenneth R Horlick Primary Examiner

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08/17/06